

138 Grand View Avenue
San Francisco, CA 94114
(415) 826-7836
FAX: (415) 824-1003

Chloe-Alexa Milne

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VIA FACSIMILE: (301) 827-6870

July 16, 1999

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive
Rockville, MD 20857

RE: 99P-1340/CP 1

Petition to Have "Eternity eau de parfum" Declared Misbranded

Dear Sir or Madam:

My health has been severely damaged by other people's fragrance use, most particularly that of my former coworkers, who subjected me to seven weeks of overpowering fragrance fumes, despite the fact that they knew of my extreme fragrance sensitivity before I started the job. Due to this prolonged exposure I have suffered severe physical, emotional and economic damage. Almost eight years of superb asthma control, on the same medications at the same doses, was utterly destroyed! I have been rendered drastically more sensitive not only to fragrance products but to all other chemicals as well ("global chemical sensitivity"). Now, only a momentary exposure to a miniscule amount of virtually any chemical substance can trigger a very severe reaction, with a much wider range of possible symptoms, including dizziness, disorientation, and even loss of consciousness!

I can no longer "compete in the general labor market." Fragrance-free workplaces are virtually impossible to find; therefore, my only option is to work at home, severely limiting both my choices of work available and my income potential. I have eight years of legal secretarial experience. If I could return to that field, I could earn \$37K+ per year. I now live on Social Security payments.

I have also lost my personal freedom. I can no longer attend movies, church, the theater, parties, classes, or weddings, (even my own nephew's), etc. I cannot enter most people's homes nor allow them to enter mine. I cannot even shop where I choose. All travel is risky. I cannot board a bus (I have no car), train, or airplane without risking perfume exposure and subsequent illness. In order to see my son and his family in Pennsylvania, I risk air travel once a year, but always with a good deal of "fear and trepidation." This chemical sensitivity will never go away. I am stuck with it for the rest of my life. I am a very friendly, sociable person by nature, but am now forced to lead a very isolated and rather lonely life; and I resent it!

"...yearning to breathe free..."

99P-1340

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In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded. I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 740.10 specifically states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning The safety of this product has not be determined."

As the petition shows, "Eternity" contains toxic ingredients and ingredients whose safety has not been substantiated. There is no warning on its packaging. NOTE: In 1991, the Environmental Protection Agency (EPA) conducted a study of the chemicals found in fragrance products. Their analyses revealed the presence of harmful chemicals in all of the products they studied. An excerpt from that study's findings, titled "The Twenty Most Common Chemicals Found in Thirty-One Fragrance Products," (available on the Internet) names each of those chemicals and lists the various physical symptoms which they are known to cause.

We all have a right to know the status of safety testing of the ingredients in products such as "Eternity." Chemical exposure is a serious health hazard! Without such information, how can we hope to protect our families and ourselves? Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, fumes from the chemicals currently used in these products permeate the air, and thus may effect the health of many people, including those afflicted with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, care givers and teachers.

ALL FRAGRANCE PRODUCTS ARE HEALTH HAZARDS, and "ETERNITY" is one of the WORST! Please, I beg you, give very careful consideration to this petition to have Calvin Klein's "Eternity eau de parfum" declared misbranded.

Thank you for your kind attention.

Very truly yours,

Chloe-Alexa Milne

cam

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facsimile transmittal

To: DOCKETS MANAGEMENT BRANCH
THE FOOD AND DRUG ADMINISTRATION

Fax: (301) 827-6870

From: CHLOE-ALEXA MILNE

Date: July 16, 1999

Re: Petition to have "Eternity eau de parfum"
Declared Misbranded

Pages: 3

CC: N/A

☐ Urgent

☐ For Review

☐ Please Comment

☐ Please Reply

☐ Please Recycle

NOTE: This is a repeat transmission. The copy transmitted yesterday contained a typographical error on the second page.